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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,409	06/05/2001	Markus H. Frank	81994/279322	1825

7590 04/02/2003

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[REDACTED] EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/873,409	FRANK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 January 2002.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 18-26 and 30-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 18-26 and 30-40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>15</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

### **DETAILED ACTION**

Amendment (Paper No. 14) was received and entered. The duplicate copy of IDS (Paper No. 10) was also received and entered as Paper No. 15.

Claims 18-26, 30-40 are pending and examined on merits.

#### ***Claim Rejections - 35 USC § 112***

Rejection of claims rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is moot** because either applicant cancelled the claims.

Rejection of claims rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention **is also moot** because applicant cancelled the claims.

#### ***Claim Objections***

Objection of cancelled claims is moot and objection of claims 39 and 40 are withdrawn in view of amendment.

#### ***Claim Rejections - 35 USC § 112***

Rejection of cancelled claims rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is moot. Rejection of claims 39 and 40 is withdrawn because the rejection was based on the now cancelled claims.

#### ***Claim Rejections - 35 USC § 101***

Claims 18-26, and 30-40 remain rejected for reason of record under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial, and a credible asserted utility or a well established utility.

Applicant argues since the proteins encoded by the instantly claimed nucleic molecules have high degree (68 %) of structural homology to proteins involved in multi-drug resistance, the proteins encoded by the instantly claimed nucleic molecules are also expected to function in multi-drug resistance. This argument is not persuasive for the reason of record (see the last paragraph of page 4 to page 6 line 5). The art recognizes that protein function could not be predicted based on structural similarities. Further the Office does not understand what is the basis of applicant's assertion that the proteins encoded by the instantly claimed nucleic acid molecules have 68 % homology to human MDR1 and MDR3. See page 17 lines 28 of the instant specification. The search conducted by this Office did not reveal such homology, for example, instantly claimed SEQ ID NO:15 encodes the putative SEQ ID NO:7 protein which appears to have about 57 % homology to human MDR1. See the attached sequence alignment of instant SEQ ID NO:7 against human MDR1 protein.

Applicant further argues that the proteins act as transporters as determined using antibody studies but this assertion is not persuasive because the specification does not provide any scientific evidence to support such assertion. Note the paragraph bridging pages 18 and 19 of the instant specification. The specification does not teach if any of the eight proteins encoded by the instantly claimed nucleic acid molecules are expressed in vivo, let alone transporter of anything. The specification says that polyclonal antibody raised using two epitopes listed as SEQ ID NOs 18 and 19 were used to check various functions of the proteins but the specification does not provide a single figure or table for the Office to evaluate applicant's various assertions about the functions of the proteins encoded by the instantly claimed nucleic acid molecules. The art recognizes the main disadvantage of a polyclonal antibody is its potential to cross-reactivity. Since the specification does not teach what controls are used to eliminate the possibilities of the polyclonal antibodies being cross-reacted with other P-glycoproteins that are not encoded by the instantly claimed nucleic acid molecules, applicant's assertion that the proteins are involved in transporter or reduce cytotoxicity is not persuasive.

Applicant further argues that some SEQ ID NOs are preferentially expressed in human melanoma cells but the specification does not provide any figures or tables for the Office to evaluate applicant's conclusion. It is not clear whether the melanoma cells used were clinical samples or cell lines, or what controls were used. The specification does not provide any evidence to support applicant's conclusion, therefore the Office maintains that the asserted utility is not credible.

Claims 18-26, and 30-40 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial, and a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

#### **NEW GROUNDS OF REJECTION**

##### ***Claim Rejections - 35 USC § 112***

Claim 39 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 recites "vector comprising a distinct coding element consisting of" but it is not clear what the metes and bounds are for the limitation.

##### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu  
March 27, 2003

*Mary Mosher*  
MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800